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Michael E. Moseley

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Mark A. Litman & Associates, P.A.
7001 Cahill Road, Ste. 15A
Edina, MN 55439

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Please find below and/or attached an Office communication concerning this application or proceeding.

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1 RECORD OF ORAL HEARING
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3 U.S. PATENT AND TRADEMARK OFFICE
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8 BEFORE THE BOARD OF PATENT APPEALS
9 AND INTERFERENCES
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14 *Ex parte* MICHAEL E. MOSELEY and JOHN KUCHARCZYK
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19 Appeal 2010-009722
20 Application 09/606,137
21 Technology Center 3700
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27 Oral Hearing Held: April 10, 2012
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34 Before ERIC GRIMES, STEPHEN WALSH, and JACQUELINE WRIGHT
35 BONILLA (via videoconference), *Administrative Patent Judges*.
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39 APPEARANCES:
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41 ON BEHALF OF THE APPELLANTS:
42 MARK A. LITMAN, ESQUIRE
43 Mark A. Litman & Associates, P.A.
44 7001 Cahill Road, Suite 15A
45 Edina, MN 55439
46
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48 The above-entitled matter came on for hearing on
49 Tuesday, April 10, 2012, commencing at 1:00 p.m., at the
50 U.S. Patent and Trademark Office, 600 Dulany Street,
51 Alexandria, Virginia, before W. Brett Bayley, Notary Public.

1 P R O C E E D I N G S

2 1:44 p.m.

3 THE USHER: Good afternoon. Calendar Number 20,
4 Appeal Number 2010-009722, Mr. Litman.

5 JUDGE GRIMES: Thank you. Good afternoon, Mr.
6 Litman.

7 MR. LITMAN: Good afternoon. Here's my card.

8 JUDGE GRIMES: One of our Judges is participating
9 by videoconference here so there is a bit of a lag. So if
10 there is a question --

11 MR. LITMAN: Very good.

12 JUDGE GRIMES: -- give him a chance.

13 MR. LITMAN: I speak slowly, try to, anyway. Good
14 morning.

15 JUDGE GRIMES: Good afternoon. You'll have 20
16 minutes to make your arguments.

17 MR. LITMAN: Yes.

18 JUDGE GRIMES: And you can get started whenever
19 you're ready.

20 MR. LITMAN: I'm here on appeal with regard to the
21 technology which I am certain you're familiar with, having
22 reviewed the case. To me, the critical issue is that all of
23 the claims require sensing of a property in the region of a
24 patient under examination and the use of the sense property

1 to provide information relating to cell chemistry that is
2 indicative of cell activity or inactivity.

3 The examiner has rejected this under 35 U.S.C. 102
4 over Majors, and Majors does not show the substance of what
5 this invention is, as claimed. If you look at Majors, every
6 example but one of Majors, and every disclosure of Majors
7 but this one example, is basically an autopsy. That is not
8 non-invasive examination.

9 He takes the cells before he implants them and
10 measures their properties, looks at them, in effect,
11 implants them, and in all but one case kills the animals,
12 takes the cells out and looks at them again under various
13 diagnostic techniques.

14 He does not take a living animal and sense them by
15 non-invasive activity to detect sense property relating to
16 cell chemistry. The only example, in fact, where Majors
17 uses a non-invasive property is in example 5 where he says
18 with two of the surviving monkeys -- meaning he has already
19 killed the others to test their cell status -- he performs
20 an MRI to test for seeing a tumor or nodule. That is all.
21 There is absolutely no use of any sensing to detect
22 properties of cell activity.

23 JUDGE GRIMES: Now, if they had found a tumor,
24 would that have indicated cell viability?

1 MR. LITMAN: No. What it indicates is that a
2 tumor has grown. The cells could still be viable. But,
3 again, we're not just looking for cell viability. This is a
4 test procedure for non-invasively detecting specifically
5 sensed properties of cell activity.

6 The cells can both form tumors -- that's an active
7 cell, and they can form normal cells. You wouldn't want the
8 cells to form. As both Majors says in his background and we
9 say in the background of our invention, tumor formation is a
10 problem with immortal cell implantation.

11 But what you want to do is not merely find the
12 cells -- or, the tumors when they are at large enough state
13 by sensing the cell activity, as we point out in the
14 specification. You can earlier detect the activity of the
15 cells that might lead to tumor or nodule formation because
16 you can sense chemical activity much earlier in the state of
17 the cell activity in the brain, rather than waiting until
18 you can see a viable tumor.

19 So the properties, the method that we are
20 performing here -- and basically what this does, if you look
21 at some of our later claims, when there is cell activity,
22 different cells at different kinds of activity, and they
23 change the chemical environment within the fluids around
24 those cells.

1 In specific claims, we make detection of $^{17}O_2$ to
2 $H_2^{17}O$ water by MRI technology. MRI identifies the presence
3 and the difference in those materials as a sensed property
4 caused by cell chemistry. There are also sodium functions
5 that are specifically recited in the claims that are nowhere
6 to be found in Majors. Majors is nothing more than giving
7 an MRI, a look at the brain, a look at the implant itself
8 and see if there's a tumor. That has nothing to do with the
9 cell activity. If he tested --

10 JUDGE WALSH: Mr. Litman, could you explain why
11 the procedure Majors did with and without gadolinium was not
12 observing a property that had to do with cell chemistry
13 related to cell activity?

14 MR. LITMAN: Yes, definitely. Gadolinium is a
15 contrast agent. When you use MRI, you get little background
16 differentiation between the types of cells and tissues that
17 are there. With gadolinium present, it tends to emphasize
18 types of cells that absorb material.

19 Now, if you had a fully functional cell and you
20 put gadolinium in, you'll see a clear mass, and you'll just
21 see that clear mass over the background. You're not seeing
22 a sense property of cell activity, you're just seeing the
23 cells.

24 All this does is make the background lighter, the

1 foreground darker. It has nothing to do with sensing
2 properties relating to cell chemistry that is indicative of
3 cell activity or inactivity. All we're doing is making a
4 more contrasting image.

5 The other techniques, such as MRI and looking for
6 responses in particular wavelengths due to the chemistry
7 that is produced by the cell is totally different than
8 merely taking an image of the cell. That's all he does in
9 this one example is take an image of a cell.

10 What we have specifically and in more detail in
11 the dependent claims for the type of cell activity chemistry
12 that we're examining is a sensed property -- and that is a
13 variation in the wavelengths and frequencies of the
14 responses in the area due to changes in chemistry caused by
15 cell activity -- that is wholly different, wholly different
16 from just looking and saying there is a tumor, there is not
17 a tumor.

18 JUDGE BONILLA: Let me ask you about claim 5,
19 because that one doesn't have a lot of the language that
20 you're talking about in a dependent claim.

21 MR. LITMAN: I'm sorry, I can't hear you.

22 JUDGE BONILLA: I'm sorry, claim 5, which is the
23 sensing of property.

24 MR. LITMAN: All right.

1 JUDGE BONILLA: What if sensing a property is
2 sensing a tumor?

3 MR. LITMAN: All right, let me look at claim 5.
4 I've got an awful lot of pages here, okay.

5 JUDGE BONILLA: It says, sensing a property within
6 a region. So let's say sensing a tumor within a region,
7 tumor being a property --

8 MR. LITMAN: All right.

9 JUDGE BONILLA: -- is invaded from sensing
10 property to indicate cell viability where that property is
11 resulting from, for example, cell growth or cell death, cell
12 activity --

13 MR. LITMAN: And, remember, this is -- cell
14 viability indicated by a property in cell chemistry
15 resulting from an event selected from. What this is, this
16 is cell chemistry. This is not merely the cell itself.
17 This is sensing a change in the environment due to changes
18 in chemistry in that environment due to changes in cell
19 activity. When cells die, they give off different
20 materials.

21 JUDGE BONILLA: How do you respond to --

22 MR. LITMAN: And you sense that.

23 JUDGE BONILLA: How do you respond to the
24 statement that cell chemistry could just be, you know,

1 active cell growth like you would see in a tumor?

2 MR. LITMAN: I'm sorry, I still can't hear you.

3 JUDGE BONILLA: How would you respond to the idea
4 that cell chemistry could even be just a massive doubling of
5 cells, like you would see in a tumor?

6 MR. LITMAN: Doubling the cells? That's merely a
7 change in size. It has nothing to do with a change in cell
8 chemistry. All he is doing is looking, and all of his
9 examinations of change in the growth of the cell were done
10 postmortem.

11 The only example where he does anything *in vivo* is
12 looking to see if a tumor is there or not. At no time does
13 he ever say, I am going to examine the environment around
14 the cells, sense properties as a result of this external
15 stimulations, and determine changes in chemistry in that
16 environment which are indicative of changes in cell
17 chemistry.

18 If all you were doing was saying, I'm going to
19 take an MRI, the cells are larger now, great, or there's
20 tumors there, great, that's totally different from what
21 we're doing. And this also gives a much earlier ability to
22 respond to deficiencies in implantation.

23 One of the big problems of implantation is, you
24 put in the material and you have to wait until the tumor

1 grows before you can see it, and by then your patient has
2 lost all the benefits of the implantation and you have to
3 have another surgery.

4 If you go in at this stage where you can't even
5 visualize the tumor and you see the change in cell
6 chemistry, you can do an intervention at that point with
7 subsequent chemicals, additional medical treatment where
8 you've got a better-performing implantation.

9 This is wholly different from waiting until your
10 patient is dying to see that he's got a problem with this
11 implantation. This measures gigagram levels of drugs in the
12 system that are indicative of changes in the cell chemistry
13 so you can monitor it within invasive procedures on the
14 patient.

15 This is far, far different from merely cutting out
16 the patient's brain to see if the cell implants work, or
17 taking an MRI to see if you've got visible tumors and you
18 know this implantation has failed. And all the claims are
19 so limited.

20 And remember also there are those specific claims
21 to the specific types of variations in cell chemistry that
22 are being measured that have not been touched. Local
23 lactate levels, local glucose turnover, local phosphorus
24 high energy metabolite concentrations, local F-19 labeled

1 metabolites, alterations in tissue sodium and changes in
2 conversion rates of O_2 to H_2O . Nothing in Majors approaches
3 that.

4 Nothing in the secondary teaches that that can be
5 done by an external non-invasive procedure. This is
6 definitely novel and clearly not obvious from the teaching
7 and the references. And every claim contains at least
8 sensing of a property and use of that sense data to provide
9 information relating to cell chemistry that is indicative of
10 cell activity or inactivity. It's not merely looking to see
11 if they're growing or not growing or if it's a tumor or not
12 a tumor. It's measuring the resultant environmental
13 chemistry around those cells to determine what activity
14 those cells are having.

15 JUDGE GRIMES: You have referred to the claim
16 process as being non-invasive.

17 MR. LITMAN: Yes.

18 JUDGE GRIMES: That, I assume, follows from non-
19 destructively observing a region?

20 MR. LITMAN: Yes, non-destructively observing,
21 because to invade you have to destroy. You can't get to
22 brain cells or implant cells without -- and sense the way
23 Majors is without taking the cells out. Majors always
24 biopsies the material to test except in that one example

1 where the only thing he is testing for is the presence of
2 nodules or tumors.

3 And Morcose also adds absolutely nothing to what
4 the failures are of Majors. And notice that Majors
5 emphasizes in his own disclosure that what he is doing is --
6 where is the specific language that the examiner even
7 quoted, prior to implantation, the viabilities of cells may
8 be assessed.

9 That's great, but it has no significance with
10 regard to what the viability of the cells are after
11 implantation, which is when it's most critical. All that
12 Majors does is detect the final extreme deviation in the
13 growth of tumors and nodules. That is too far down the line
14 to be useful to the majority of patients where any problems
15 are going on.

16 JUDGE BONILLA: How broadly should we interpret
17 the terms observing or sensing or using, and can those be
18 eyeballed?

19 MR. LITMAN: I'm sorry, I can't hear. I've got my
20 hearing aids on, but that's --

21 JUDGE BONILLA: I wasn't speaking very clearly.
22 How broadly should we interpret the step terms, so observing
23 or sensing or using data, can those be eyeballed, for
24 example, on the skin?

1 MR. LITMAN: You can't eyeball changes in cell
2 chemistry in the environment. There's no way you can
3 eyeball it. The only way you can eyeball it is by having a
4 monitor screen as a result of the MRI stimulation, and with
5 that stimulation having frequency responses being displayed
6 that are indicative of the specific cell chemistry changes.

7 There isn't a single type of observation that
8 would be made for these different cell chemistries because
9 they would appear at different frequencies, different types
10 of responses. You cannot observe cell chemistry any more
11 than you can observe, you know, oxygen and hydrogen, water
12 splitting up into OH and H inside of a water bottle. You
13 can't see it.

14 JUDGE BONILLA: So you assume that one of the
15 steps in the claim is actually observing cell chemistry?

16 MR. LITMAN: Yes. It is a definitive step that
17 there be the active effort of --

18 JUDGE BONILLA: Because the claim --

19 MR. LITMAN: -- nondestructively observing.

20 JUDGE BONILLA: -- that we're seeing, using data
21 to indicate cell viability, and this is -- cell viability is
22 indicated by the cell chemistry. And you interpret that to
23 mean that they are actually measuring cell chemistry in some
24 way? Am I reading that correctly?

1 MR. LITMAN: I think a little more broadly than I
2 would interpret it. It's nondestructively observing a
3 region of a patient where the cells have been transplanted,
4 and it's sensing a property within said region, and that
5 property being directly related to cell chemistry resulting
6 from classes of events. There has to -- the cell chemistry
7 has to result from cell activity. This is -- and growth
8 itself is not a cell chemistry property that you sense.

9 JUDGE BONILLA: So sensing a property is sensing
10 the cell chemistry?

11 MR. LITMAN: Yes, you sense -- exactly. Okay.
12 All right, I know I got one comment I wanted to make on
13 Morcose, but I will in a second here. Oh, okay, also the
14 specific methods are not shown in Morcose either. He has
15 absolutely no instruction or evidence that would teach the
16 obviousness of the use of the sensing of those kinds of
17 properties for any purpose whatsoever.

18 JUDGE GRIMES: All right, I think we understand
19 your argument.

20 MR. LITMAN: I hope so.

21 JUDGE GRIMES: The panel has no more questions.

22 MR. LITMAN: If I may put in the record, this is
23 approximately my 450th appeal to the Patent and Trademark
24 Office.

1 JUDGE GRIMES: Wow.

2 MR. LITMAN: And almost to the day the 40th year
3 of my going into private practice after leaving the Patent
4 Office, and I am now going to be taking a position with the
5 University of Nevada Las Vegas in their intellectual
6 property transfer department, as well as continuing my
7 practice. So, if I may quote Bob Dylan, if you're not
8 working to be reborn, you're living to die. So here we go.

9 JUDGE GRIMES: Best of luck.

10 MR. LITMAN: Thank you all.

11 JUDGE GRIMES: We're off the record.

12 [WHEREUPON, the proceedings were concluded at
13 2:02 p.m.]

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